

## REMARKS/ARGUMENTS

### Allowable Subject Matter

The Examiner has indicated that claims 81-82 are allowable. Applicant appreciates the Examiner's indication of allowable subject matter. No changes have been made to claims 81 and 82.

### In the Claims:

Claims 44-63 and 79-86 are currently pending in the present application. Claims 1-42 have been previously canceled. Claims 43, and 64-78 have been previously withdrawn. Claims 44, 50, 79, and 83 are currently amended. New claims 84-86 have been added.

### Rejection of Claims 44-48, 50-55, and 83 Under 35 U.S.C. § 112

The Examiner objected to claims 44-48, 50-55, and 83 under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement. More specifically, the Examiner asserts that there is no support in the specification for the recitation of a "non-porous" sleeve and, that due to the possibility of air remaining in the inner chamber (20) and/or intermediate air chamber (34) of the present invention, the recitation that "substantially no air pockets remain within said prosthetic limb socket when said residual limb has been fully drawn into said socket" is inaccurate. Applicant has amended claims 44, 50, and 83 to more accurately describe the subject matter therein, and has referenced particular portions of the written description to support said amendments.

Applicant has amended claims 44 and 50 to recite a "substantially impermeable" sleeve, as opposed to the previously recited "non-porous" sleeve. Applicant respectfully submits that there is support for such amendment both in the inherent properties of silicone materials, and elsewhere in the written specification. Particularly, it is stated that when no liner is used, "the inner socket is typically designed to ... provide an air-tight seal between the residual limb and the outer socket" (US 5,702,489; column 1, lines 22-27). It is also stated that "[o]nce the residual limb is inserted comfortably within the socket the valve is closed, forming a suction such that the socket will be secured to the amputee's residual limb" (US 5,702,489; column 3, lines 42-45). Therefore, it can be understood that when no sleeve (liner) is used, a seal is formed between the inner surface of the prosthetic socket and the "substantially impermeable" skin of the amputee's residual limb.

Suction retention of the prosthetic limb on the residual limb is also employed when a sleeve (liner) is worn by the amputee. Consequently, the liner material must be capable of forming a seal with the socket interior in a similar manner to the skin of the residual limb. In fact, it is specifically stated that "[t]he silicone sleeve ... provides a seal between the [residual] limb and the socket when the limb is tightly fitted in the socket" (US 5,702,489; column 5, lines 55-58). Therefore, Applicant submits that if a permeable sleeve were used in the present invention, the required seal could not be formed because air could freely pass through the permeable liner material and into or out of the socket.

The Examiner asserts that Fishman et al. (US 5,007,937) teaches a porous sleeve that is capable of forming a seal with the interior of a prosthetic socket.

Applicant strongly disagrees with the Examiner's assertion. While the majority of the stump sock of Fishman et al. is of porous construction (e.g., nylon, orlon, cotton, or wool), the sock material itself is not used to provide a seal with the socket. Rather, because the porous nature of the sock material will not permit a vacuum to be maintained in the prosthetic socket, the sock must be modified by impregnating a small band of the porous sock material with a rubberized material. It is this small band of rubberized material, and only this small band of rubberized material (not the porous material) that provides a seal between the residual limb and the prosthetic socket. Thus, Fishman et al. does not teach a porous stump sock (liner) that is capable of providing sealing contact with a socket. In fact, Fishman et al. seems to teach that it is not possible to provide a seal between a residual limb and a prosthetic socket using a porous liner - otherwise the rubberized material would be unnecessary

Applicant has also amended claims 44, 50 and 83 to clarify that substantially no air pockets remain between "a distal end of [a] residual limb and a proximal surface of [a] base," "a distal end of [a] residual limb and a base-plate," or "a distal end of [a] residual limb and a bottom of a receiving cavity," respectively. Applicant believes this language to more clearly describe the elimination of air pockets by the present invention than did the old language, which recited "substantially no air pockets remain within said prosthetic limb socket when said residual limb has been fully drawn into said socket." While there could be very small amounts of air remaining in the inner chamber (20) and/or intermediate air chamber (34) of the present invention, it is ensured that substantially all air pockets will be expelled from between the distal end of the residual limb and the mating structure provided therefor near the bottom of the socket. It should

be noted that both the inner chamber (20) and intermediate air chamber (34) reside beneath the portion of the prosthetic socket interior that is designed to mate with the distal end of the residual limb.

Support for the elimination of air pockets by the present invention is indicated by the statement that allowing the distal end of a residual limb to cover and seal off valves prior to full insertion thereof ... "may result in an undesirable air pocket between the distal [end of the] limb and the distal end of the sockets" (US 5,702,489; column 2, lines 26-28). More particularly, it is stated with respect to one particular embodiment of the present invention that "the distal position of the valve plate assembly guarantees that substantially no air pockets are left between the patient's residual limb and the interface cushion **28**" (US 5,702,489; column 6, lines 11-13).

Applicant submits that claims 44-48, 50-55, and 83 now recite allowable subject matter. As such, Applicant respectfully submits that the Examiner's 35 U.S.C. § 112 rejection of claims 44-48, 50-55, and 83 may now be properly withdrawn.

Rejection of Claims 79 and 80 Under 35 U.S.C. § 102(b)

The Examiner rejected claims 79 and 80 under 35 U.S.C. § 102(b) as being anticipated by Toles (US 980,457). As the Applicant does not believe Toles to teach the subject matter of claims 79 and 80, the rejection is respectfully traversed.

In making the present rejection, the Examiner equates the tube (18) portion of the valve of Toles with a base. Applicant respectfully submits that element (18) of Toles is not a base, and is also not equivalent to the base recited in claims 79-80 of the present application. Toles specifically states that element (18) is a tube, which is used

to transfer moisture from within the sack (12) - it is not a base. However, even if the two elements could somehow be equated, Toles still does not teach that a periphery of the base provides an air-tight seal with the socket wall. As can be seen, the periphery of the tube (18) in Toles does not come anywhere near the interior walls of the socket (2). Certainly, therefore, Toles cannot teach that such an airtight seal is provided by an annular projection extending from the base (as recited in claim 80).

Toles also fails to teach an attachment mechanism, *carried on the base*, for facilitating releasable attachment of an external prosthetic limb assembly to an exterior distal end of the socket. For example, such an assembly might commonly include the lower supporting structure of a prosthetic leg, or a forearm and/or hand portion of a prosthetic arm. The screw (20) and nut (22) assembly of Toles referred to by the Examiner functions only to secure the *internally* residing sack (12) to a *proximal* end of the socket and to stretch the sheath within which the sack resides. The screw (20) and nut (22) assembly of Toles is not designed to connect any type of external structure to the exterior distal end of the socket (2). In fact, no portion of the screw (20) and nut (22) assembly extends through the socket (2) wall, nor is there any means provided for passage of an external element through the distal end of the socket (2) and to the screw and/or nut.

### CONCLUSION

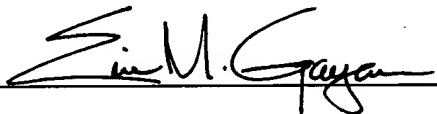
The Applicant has amended claims 44, 50, 79, and 83 to more clearly describe the present invention. The Applicant has also distinguished the subject matter of the present invention over the teachings of the reference cited as prior art by the Examiner.

Therefore, the Applicant respectfully submits that the present application is now in condition for allowance, and entry of the present amendment and allowance of the application as amended is earnestly requested. Telephone inquiry to the undersigned in order to clarify or otherwise expedite prosecution of the present application is respectfully encouraged.

Respectfully submitted,

Date: 5-19-04

By:

A handwritten signature in black ink, appearing to read "Eric M. Gayan", is written over a horizontal line.

Eric M. Gayan  
Registration No. 46,103  
Standley & Gilcrest LLP  
495 Metro Place South  
Suite 210  
Dublin, Ohio 43017-5319  
Telephone: (614) 792-5555  
Facsimile: (614) 792-5536  
E-mail: egayan@standleyandgilcrest.com